

1995 Michigan Prostate Cancer Consensus Conference

Consensus Statements and Recommendations for Further Study

Sponsored by:
*The American Cancer Society, Michigan Division
The Michigan Department of Public Health
The Michigan Public Health Institute*

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Introduction

Prostate cancer is a serious disease, killing more than 1,200 men each year in Michigan alone and afflicting thousands of others, severely impacting both their health status and quality of life. In an effort to minimize the devastating effects of this disease, the Michigan Department of Public Health, the Michigan Division of the American Cancer Society, and the Michigan Public Health Institute joined together to co-sponsor the 1995 Michigan Prostate Cancer Consensus Conference.

For two days in June, approximately 135 Michigan healthcare professionals and consumers from across the state -- including some of the nation's top experts on prostate cancer -- gathered at the Flint site of the conference to examine critical issues related to the screening, diagnosis, and medical management of prostate cancer patients, and to develop consensus recommendations for patients, professionals and the public. This document reflects the results of that gathering.*

Among the specific conference objectives:

To identify areas of consensus about prostate cancer in order to inform physicians about screening/early detection, diagnosis, and treatment of prostate cancer patients, in light of evolving research.

To identify educational messages that should be provided to all men concerning prostate cancer risk, early detection, and treatment.

To recommend appropriate role(s) for the Michigan Department of Public Health in prostate cancer control.

Among the projected outcomes of the conference:

To publish a Consensus Conference report that will serve as a guide for the Michigan Department of Public Health in its efforts to reduce the burden of prostate cancer on citizens of Michigan by optimizing the screening, diagnosis, and medical management of prostate cancer patients.

**Note: Throughout this document, the terms "screening" and "early detection" are used interchangeably. Both refer to non-symptom-prompted testing, whether it is office- or population-based.*

To make the Consensus Conference report available to physicians and health care professionals statewide.

To disseminate conference consensus statements and recommendations to providers, patients, and the public via a post-conference news conference.

To produce a series of printed and audio-visual materials designed to educate the public about prostate cancer control.

Conference Format

Conference Organization

Recognizing the seriousness of the health issues surrounding prostate cancer, the Michigan Department of Public Health (MDPH), the American Cancer Society, Michigan Division (ACS), and the Michigan Public Health Institute (MPHI) formed a partnership to organize and sponsor a statewide Prostate Cancer Consensus Conference under the leadership of Arthur Porter, MD, president of the Michigan Division of the ACS and chairperson of the Radiation Oncology Department at Wayne State University in Detroit.

A Conference Planning Committee was formed, consisting of Dr. Porter; Ronald Davis, MD, medical director of MDPH in Lansing; Fred Lee, MD, director of the Prostate Center at Crittenton Hospital in Rochester; James Montie, MD, clinical director of the Urologic Oncology Program at the University of Michigan in Ann Arbor; Joseph Oesterling, MD, director of the Michigan Prostate Institute at the University of Michigan; G. Marie Swanson, PhD, MPH, director of the Cancer Center at Michigan State University in East Lansing; and representatives of the ACS, MDPH, MPHI, and Wayne State University.

Members of the Conference Planning Committee planned 12 roundtable sessions to address critical prostate cancer issues within the areas of "Screening", "Treatment and Support", and "Flex Topics". They then selected experts in these areas to facilitate and lead the roundtable discussions during the conference.

In turn, the 12 roundtable leaders created a roster of conference participants, taking care to invite a mixture of prostate cancer medical experts, prostate cancer providers, prostate cancer survivors, men at risk for prostate cancer, economists, risk managers, and prostate cancer advocates. Individuals were invited to participate in the conference based upon their expertise, as well as their geographical base within the state.

In this way, conference organizers worked to ensure that participants represented not only a cross-section of disciplines associated with prostate cancer, but also a cross-section of the state's population.

Roundtable Discussions

Each meeting participant attended one of 12 separate roundtable discussions addressing specific critical issues concerning prostate cancer management. Discussion leaders were responsible for prioritizing topics within each issue, developing statements of consensus, and identifying areas requiring further investigation. The 12 roundtable topics and leaders included the following:

Screening:

Epidemiology (Leader: Ray Demers, MD, MPH, Karmanos Cancer Institute, Detroit)

Early Detection (Leader: Peter Littrup, MD, Department of Radiology, School of Medicine, Wayne State University, Detroit)

Special Populations (Leader: Isaac Powell, MD, Department of Urology, School of Medicine, Wayne State University, Detroit)

Treatment and Support:

Cryosurgery (Leader: Duke K. Bahn, MD, Department of Radiology, Crittenton Hospital, Rochester)

Radiation (Leader: Jeffrey Forman, MD, Department of Radiation Oncology, Harper Hospital, Detroit)

Surgery (Leader: Edson Pontes, MD, Department of Urology, School of Medicine, Wayne State University, Detroit)

Systemic Therapy (Leader: Muhyi Al-Sarraf, MD, Cancer Center, Providence Hospital, Southfield)

"Wait-and-See" (Leader: James Montie, MD, Urologic Oncology Program, University of Michigan, Ann Arbor)

Flex Topics:

Quality of Life (Leader: Charles W. Given, PhD, Department of Family Practice, Michigan State University, East Lansing)

Health Economics/Managed Care (Leader: Michael Chernew, PhD, Department of Health Management and Policy, School of Public Health, University of Michigan, Ann Arbor)

Research (Leader: Kenneth Honn, PhD, Department of Radiation Oncology, School of Medicine, Wayne State University, Detroit)

Risk Management (Leader: Patricia Fowler, RN, MPA, Risk Management & Insurance, Michigan State University, East Lansing)

Summary Sessions

Following the roundtable discussions, Consensus Conference participants gathered in two concurrent sessions in an effort to summarize the roundtable discussions. Each summary session addressed specific topic areas. The "Screening" session (led by Dr.

Fred Lee) included discussions on epidemiology, early detection, special populations, research, risk management, health economics, and quality of life issues. The "Treatment and Support" session (led by Dr. James Montie) included discussions on surgery, cryosurgery, radiation, the "wait-and-see" approach, systemic therapy, research, risk management, health economics, and quality of life issues.

Closing General Session

This session was led by Dr. Arthur Porter and attended by all conference participants. Dr. Porter invited each of the 12 roundtable leaders to summarize their group's points of consensus and introduce topics which their group would like to see further investigated. Following that, each topic was opened to discussion and a general consensus was reached. Key issues and the specific results of each topic discussion follow.

Key Public Health Issues

A number of concepts can be considered central public health issues in prostate cancer control. Among them are the following:

- *The high incidence of prostate cancer makes it an important target for cancer control measures.*
- *Increased use of prostate specific antigen (PSA) testing has led to a doubling of identified early stage prostate cancer cases since 1989.*
- *Both African-American men and men with a family history of prostate cancer are at particularly high risk for prostate cancer.*
- *Currently, there is insufficient evidence to support or contradict the premise that early detection decreases either mortality or morbidity rates associated with prostate cancer.*
- *If early detection proves to be clinically beneficial, the following groups are most likely to benefit:*
 - *High-risk men, including:*
 - *African-American men who are between 40-75 years of age and have a life expectancy of more than 10 years, and*
 - *men with a family history of prostate cancer who are between 40-75 years of age and have a life expectancy of more than 10 years; and*
 - *All other men between 50-75 years of age who have a life expectancy of more than 10 years.*
- *PSA testing is currently the most reliable method for the early detection of prostate cancer.*
- *Before deciding to be tested for prostate cancer, every man needs to discuss with his health care provider the relevance of testing for himself, including the possible side effects of treatment and the implications for his quality of life if prostate cancer should be found.*

- *There currently is no standardized treatment regimen for prostate cancer patients. Thus, multi-disciplinary studies are needed to provide objective comparative data (i.e., efficacy, adverse effects, quality of life, and economic parameters) concerning therapeutic modalities. These studies must include the identification and use of uniform therapeutic endpoints (i.e., defined measures of efficacy and toxicity).*
- *The dilemma for men and their physicians is that screening, treatment, failure to screen, and failure to treat each may have negative consequences for the individual. The former two are associated with the potentially adverse effects of therapeutic interventions, while the latter two are associated with the potential for disease progression.*
- *Research is needed to answer questions concerning:*
 - *Effectiveness, costs, and complications, in relationship to the benefits of early detection methods and of treatment alternatives; and*
 - *Effectiveness of various strategies for communicating information about prostate cancer to the general public, high-risk men, men diagnosed with prostate cancer, and health professionals.*

Consensus Statements and Issues for Further Study

The following section summarizes the specific consensus statements gleaned from discussions of each topic, and also identifies topics which require further investigation. Some of these statements also were presented in the previous section, "Key Public Health Issues in Prostate Cancer Control".

Screening: Epidemiology

Consensus Statements:

- 1. The incidence of prostate cancer in the United States has been rising for several decades, and has shown a marked increase since 1988. Presumably, this rise is due to an increase in early stage diagnoses. Among Caucasian men, the most recently available data suggests a lower incidence rate of prostate cancer in 1993, compared with 1992.*
- 2. The incidence rate of late stage prostate cancer has decreased over the last four years.*
- 3. The annual incidence and mortality rates of prostate cancer in the United States remain higher among African-American men than among Caucasian men. However, two recent trends have been identified. The first indicates a relatively greater rise in prostate cancer incidence rates since 1988 among Caucasian men, relative to African-American men, primarily due to PSA screening differences. The second demonstrates that mortality*

rates associated with prostate cancer recently have risen more rapidly among African-American men than among Caucasian men.

4. Age, race, farming occupation, and family history consistently have been identified as risk factors for prostate cancer.

5. Modifiable factors, such as diet and lifestyle, have not been consistently associated with an increased risk of prostate cancer.

Issues Requiring Further Study:

1. The increased use of PSA testing since 1989 correlates with the increase in early stage diagnoses and the apparent decrease in late stage diagnoses over the last four years. However, the benefits of migration and the impact of early treatment remain uncertain, and long term follow-up studies are needed.

2. The lower incidence of prostate cancer among U.S. Caucasian men in 1993 compared with 1992 may be due to a leveling off of the initial impact of PSA testing in detecting previously undiagnosed cases. Continued data accumulation is needed to further determine the implications of this observation.

3. Sub-population studies are needed to determine differences in risk factors related to ethnicity.

4. Interactions of risk factors should be studied to enhance healthcare providers' ability to identify high-risk individuals.

5. Studies are needed to identify biological (i.e., genetic) markers indicative of a high risk for prostate cancer and disease progression.

6. Migration studies have demonstrated that men tend to assume the prostate cancer incidence rate of the country in which they currently are residing. This indicates the existence of significant, non-inherited risk factors (e.g., diet, environment, etc.). However, the specific risk factors related to this phenomenon have not been identified and require further study.

Screening: Early Detection

Consensus Statements:

1. The high incidence of prostate cancer makes it an important target for cancer control measures.

2. *Currently there is insufficient evidence to support or contradict the premise that early detection decreases either the mortality or the morbidity associated with prostate cancer.*
3. *PSA testing is the most reliable method for detecting prostate cancer.*
4. *If early detection proves to be clinically beneficial, the following groups are most likely to benefit:*
 - *High-risk men, including:*
 - *African-American men who are between 40-75 years of age and have a life expectancy of more than 10 years, and*
 - *men with a family history of prostate cancer who are between 40-75 years of age and have a life expectancy of more than 10 years; and*
 - *All other men between 50-75 years of age who have a life expectancy of more than 10 years.*
5. *Thorough education for patients by well-informed healthcare providers, both before and after PSA testing, is needed to address the implications of screening and possible future therapeutic interventions.*

Issues Requiring Further Study:

1. *PSA levels are used as an indication of the need for further medical evaluation for the presence of prostate cancer. There is strong evidence to suggest that the range of PSA levels established primarily among Caucasian populations may not be appropriate in the high-risk African-American population. Therefore, further evaluation of PSA ranges is needed, particularly in high-risk populations.*

Screening: Special Populations

Consensus Statements:

1. *African-American men constitute a high-risk population for prostate cancer. In fact, the prostate cancer-associated mortality rate of African-American men 50-70 years of age is two to three times higher than that of Caucasian men of the same age group.*
2. *There is both a high incidence and a disproportionate mortality rate associated with prostate cancer in African-American men.*

Issues Requiring Further Study:

1. African-American men do not participate in early detection testing as frequently as Caucasian men, due to distrust (perhaps fear of experimentation), fear of diagnosis, and myths about cancer surgery. Studies are needed to determine the most effective ways to overcome these fears.

2. Targeted educational programs (e.g., to African-American men and to women) concerning prostate cancer issues should be developed and assessed for their effectiveness.

3. There is a need to evaluate the most efficacious age and interval for PSA testing to be done among African-American men and other high-risk populations.

4. There is a need to evaluate the cost, benefits, and risks of providing periodic PSA testing and appropriate follow-up for high-risk individuals without the economic means to obtain these interventions.

Treatment and Support: Cryosurgery

Consensus Statements:

1. Cryosurgery may be a viable treatment option for patients with localized prostate cancer and failure of radiation therapy.

2. While cryosurgery may provide therapeutic benefits in some cases, patients should be informed that this technique is presently considered an investigational therapeutic option.

Issues Requiring Further Study:

1. The clinical outcome associated with cryosurgery is highly operator-dependent, exemplifying the need for standardized protocols which need development.

2. Comparative studies are needed to evaluate cryosurgery with respect to standard therapies (i.e., surgery, radiation therapy, and systemic therapy). Such studies must address the efficacy, adverse effects, quality of life measures, and cost effectiveness associated with such treatment.

Treatment and Support: Radiation

Consensus Statements:

- 1. Radiation therapy (i.e., external beam radiotherapy, brachytherapy) is a treatment option in patients with localized prostate cancer.*
- 2. Patients with locally advanced prostate cancer require treatment intensification protocols. For these patients, clinical evidence strongly suggests that therapeutic modalities such as neoadjuvant hormone therapy, neutron therapy, dose escalation, and brachytherapy may be beneficial.*
- 3. Information concerning the potential benefits and the potential risks of these treatment options must be presented clearly to the patient before therapy is implemented.*
- 4. Post-prostatectomy radiation therapy is a treatment option in patients with recurrent or residual prostate cancer.*
- 5. Management of post-radiation residual prostate cancer or metastatic disease requires a multi-disciplinary approach.*

Issues Requiring Further Study:

- 1. Comparative studies are needed to provide objective data (i.e., efficacy, adverse effects, quality of life measures, and cost effectiveness) concerning prostate cancer treatment modalities, including radiation therapy.*

Treatment and Support: Surgery

Consensus Statements:

- 1. Surgery is a treatment option for patients with prostate cancer. Both radical retropubic and perineal prostatectomy are acceptable surgical methods, with no significant therapeutic differences.*
- 2. Low mortality rates are associated with radical prostatectomy procedures.*
- 3. Laproscopic pelvic lymphadenectomy has a limited therapeutic role prior to radical prostatectomy.*

Issues Requiring Further Study:

- 1. There is a wide range of reported incidence values of impotence or incontinence after surgery in prostate cancer patients. This may be partly attributable to underlying disease or medications. A population-based study is needed to objectively address these issues.*

2. The benefits of neoadjuvant hormonal therapy prior to prostate cancer surgery must be further evaluated in clinical studies.

Treatment and Support: Systemic Therapy

Consensus Statements:

- 1. The primary therapy for patients with symptomatic metastatic prostate cancer is androgen deprivation (i.e., LHRH-agonist and anti-androgen; or orchiectomy \pm anti-androgen).*
- 2. Hormonal therapy is an optional therapeutic modality for patients with asymptomatic metastatic prostate cancer.*
- 3. There are no data to support the use of hormonal therapy plus chemotherapy for patients with M+ prostate cancer.*
- 4. Treatment with neoadjuvant and adjuvant hormones, in combination with surgery or cryosurgery, is an investigational therapeutic option for patients with locally advanced prostate cancer.*
- 5. Data suggest that treatment with neoadjuvant and adjuvant hormones, in combination with radiotherapy, is beneficial for local prostate cancer control and disease-free survival.*
- 6. Hormonal therapy is a therapeutic option for selected "wait-and-see" patients with localized prostate cancer.*
- 7. There is no physiological basis for continued LHRH-agonist therapy after an orchiectomy.*
- 8. Active single and combination chemotherapeutic regimens have been identified as standard options for palliative utility in symptomatic prostate cancer patients who have failed hormonal therapy.*

Issues Requiring Further Study:

- 1. The benefits of continuing androgen deprivation (LHRH-agonist) in patients with progressive prostate cancer who are on hormonal therapy are still unclear, and require investigation.*
- 2. Combination therapy with chemotherapy and Sr-89 is investigational for palliation in prostate cancer patients, and requires further study.*

3. *Combination therapy with chemotherapy and radiotherapy is investigational as a curative measure for prostate cancer, and requires further study.*

4. *Due to the particular difficulty of adequately treating endocrine refractory prostate cancer patients, these individuals should be encouraged to enroll in clinical trials to identify the most clinically beneficial regimens.*

Treatment and Support: "Wait-and-See"

Consensus Statements:

1. *Patients should be aware of the fact that prostate cancer is not a dormant disease and that it has a variable growth rate.*

2. *The "wait-and-see" approach is a primary therapeutic option for some prostate cancer patients. A patient with a small, well-differentiated cancer with a Gleason score of 6 (i.e., a less aggressive cancer based on microscopic examination) may be a good candidate for a "wait-and-see" approach, especially if he has a life expectancy of less than 10 years.*

3. *Variables to consider in choosing a "wait-and-see" policy include:*

- *risk assessment of the natural history of the cancer in this particular individual's case;*
- *efficacy and adverse effects associated with the treatment options;*
- *co-morbid conditions; and*
- *the patient's motivation to avoid or delay treatment.*

4. *There are no adequate data currently available on clinical outcomes greater than 10 years post-diagnosis, using a "wait-and-see" approach.*

5. *When choosing a "wait-and-see" approach, it is vital that both the patient and the healthcare provider are educated regarding the variables that must be considered before choosing this approach. In addition, there must be periodic examinations and evaluations to monitor for disease progression; these may include PSA testing, digital rectal examination (DRE), or transrectal ultrasonography (TRUS).*

Issues Requiring Further Study:

1. *Patients must be provided with unbiased written and verbal information about their therapeutic options. Studies are needed to determine the preferred format of this information for different population groups and*

the best way to implement its dissemination in order to maximize its effectiveness.

2. It is necessary to determine the most appropriate interval for periodic examinations of patients managed by the "wait-and-see" approach.

3. It is necessary to determine the appropriate endpoint that defines when the "wait-and-see" approach should be replaced with therapeutic intervention.

Flex Topics: Quality of Life

Consensus Statements:

1. Quality of life is a primary patient management issue, particularly since long-term clinical benefits of interventions have not yet been shown. Important quality-of-life issues for men with prostate cancer include, but are not limited to: immediate and long-term impotence, urinary symptoms including

- incontinence, degraded bowel function, pain, altered social function, and treatment-associated risks.*

2. Although there is a need to refine these dimensions and their scaling methods, those measures currently identified and in use are adequate to initiate clinical evaluations.

3. All studies addressing prostate cancer treatment options should incorporate quality-of-life assessments. These assessments should come from the patients.

4. Information on quality-of-life dimensions should be paired with current data on the clinical risks and benefits of treatment options. This information should be presented to patients and physicians for use in choosing preferred treatment options.

5. Community-based prostate cancer support groups are an important resource in the quality-of-life outcomes for men with prostate cancer.

6. The patient's desire to change his treatment regimen must be recognized and considered by the health care system.

Issues Requiring Further Study:

1. A longitudinal panel study of the same patients over time is needed to compare treatment options and their outcomes with the associated quality-

of-life outcomes. Assessments should be made immediately prior to treatment, and at multiple points in time following the onset of treatment, in order to produce a comprehensive understanding of treatment alternatives as they impact recovery, disease-free intervals, and the associated quality-of-life outcomes.

2. There is a need to continue developing and refining the measures of quality-of-life dimensions.

3. There is a need to design, test, and implement effective formats (e.g., pamphlets, videotapes, CD-ROMs) for patient education. The information provided must link treatment options with the probability of their associated quality-of-life and clinical outcomes at time points following the onset of each treatment option.

Flex Topics: Health Economics/Managed Care

Consensus Statements:

1. Associated costs of a screening/early detection test, educational program, or treatment regimen may be justified if scientific evidence shows clear clinical benefits (i.e., improvement in health status and/or reduction in mortality).

2. Systematic evaluation of the economic impact of screening, educational programs, and recommended treatment protocols is needed prior to widespread implementation.

Issues Requiring Further Study:

1. Pilot studies should be carried out prior to the widescale implementation of early detection, education, or treatment recommendations in order to evaluate the associated benefits and costs.

2. In developing healthcare provider education programs, public health policy groups should stress treatment co-morbidity issues and complications that might influence both early detection and treatment decisions.

Flex Topics: Research

Consensus Statements:

1. An accessible multi-institutional prostate cancer data base and tumor tissue bank should be established.

2. Basic science issues in prostate cancer research should include a focus on the molecular mechanisms involved in carcinogenesis, tumor progression, and resistance to therapy.

3. Basic research should focus on high-risk populations and familial prostate cancer to identify potential biological factors that differentiate these individuals from sporadic cases of prostate cancer.

4. There is a need in basic science for adequate model systems, particularly animal and cell models, to study prostate cancer.

5. The need for novel therapeutics in prostate cancer patient management requires that research endeavors focus on areas such as androgen independence, gene therapy, and signal transduction therapy.

6. Translational research applies basic science to human systems. It is critical to develop and validate prognostic molecular markers to predict the likelihood of prostate cancer progression and distant metastasis.

Issues Requiring Further Study:

1. Families at high risk for prostate cancer should be identified for use in larger future basic science and translational research studies.

2. A multi-institutional registry database of high-risk families should be developed.

Flex Topics: Risk Management

Consensus Statements:

1. Information regarding the Consensus Conference should be disseminated widely in an effort to educate patients, healthcare providers, and the public about current areas of agreement and those questions that remain and require further study.

2. The information/education provided by this conference can enhance communication between healthcare providers and patients. It should promote partnering and shared decision making, including the patient's acceptance or refusal of treatment.

3. Patient education about prostate cancer screening/early detection and treatment should be in various formats (e.g., videos, booklets) and settings (e.g., workplaces, churches, physicians' offices) to support the informed consent process. The informed consent process must include discussions

between the well-informed health care provider and the man needing to make decisions about testing and/or treatment.

Issues Requiring Further Study:

- 1. Prostate cancer patient information materials should be reviewed and updated periodically, so that informed decisions can be made regarding screening and/or treatment.*
- 2. Due to the uncertainty surrounding the long-term benefits of early detection and treatment choices, a single standard of care for prostate cancer has not yet been established. Each case must be individually assessed by the healthcare professional and the patient.*

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